

PATENT
674544-2001**REMARKS**

Reconsideration and withdrawal of the restriction requirement are respectfully requested in view of the remarks herewith.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 1-29 are now pending. Claims 24 and 27 have been amended, and new claim 29 added, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that these claims, as originally presented and amended herein, are in full compliance with the requirements of 35 U.S.C. 112. The amendment to the claims and the remarks made herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§101, 102, 103 or 112.

The July 1, 2002 Office Action requested clarification of claims 23 and 27. It is believed that the Office Action should have referred to claims 24 and 27, and these claims have been amended herein to comply with the request made in the Office Action and to place the application in better condition for examination. Support for the amended claims can be found throughout the specification and in the claims as originally submitted.

New claim 29 is added to round out the scope of protection to which Applicant is entitled. Support for the new claim can be found throughout the specification and in the claims as originally submitted.

II. RESPONSE TO THE RESTRICTION REQUIREMENT

The July 1, 2002 Office Action called for restriction from among the following:

Group I: Claims 1-18, 23-24 and 26-28, drawn to a complex comprising an HLA class I molecule that comprises a T-cell binding portion and attaching means for selectively attaching said HLA class I molecule to a target cell, a pharmaceutical composition or kit thereof, and a method of preparing a medicament comprising said complex, classified in class 514 subclass 8; class 530, subclass 387.3; and class 435, subclass 975;

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- Group II: Claim 19, drawn to a method for attaching the complex of claim 1 to said target cell, classified in class 435, subclass 7.21;
- Group III: Claim 20, drawn to use of the complex in the *ex vivo* or *in vivo* amplification of cytotoxic T-cells with specificity for said recognition peptide, classified in class 435, subclass 7.21, and class 424, subclass 184.1;
- Group IV: Claim 21, drawn to a method for producing or enhancing an immunological response against a target cell, classified in class 424, subclass 184.1;
- Group V: Claims 22 and 25, drawn to a method for immunizing a patient against a disease or condition comprising administering said complex, classified in class 424, subclass 184.1.

Group I is elected, with traverse. And, as new claim 29 is similar to claim 28, it is submitted that should the restriction requirement stand, claim 29 should be added to Group I, such that applicants elect, with traverse, the claims of Group I, namely, claims 1-18, 23-24 and 26-29.

The Office Action states that the "inventions are distinct ... because ... Groups II-V contain distinct methods coupled with distinct process steps. Therefore, Groups II-V are patentably distinct, each from the other." Office Action at 2. Additionally, the Office Action states that Group I and Groups II-V are related as product and process of use. The Office Action continues that "[t]he product as claimed, the complex, can be used as an immunogen in a process of making monoclonal antibodies," which allegedly satisfies the conditions of MPEP 8.6.05(h), and makes the restriction proper. *Id.*

The MPEP lists two criteria for a proper restriction requirement. First, the invention must be independent or distinct. MPEP § 803. Second, searching the additional invention must constitute an undue burden on the examiner if restriction is not required. *Id.* The MPEP directs the examiner to search and examine an entire application "[i]f the search and examination of an entire application can be made without serious burden, ... even though it includes claims to distinct or independent inventions." *Id.*

It is respectfully submitted that the claims of the present invention, Groups I-IV, should be searched together. The claims of Groups I-V all relate to a complex comprising an HLA class

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I molecule or fragment thereof, such that any search and examination would be co-extensive for the claims of Groups I-V.

Additionally, the Examiner's attention is respectfully drawn to MPEP §808.02 which states, "even with patently distinct inventions, restriction is not (emphasis added) required unless one of the following reasons appears:

Separate classification;
Separate status in the art; or
Different field of search[.]"

Indeed, Groups I-III are all at least partially classified in class 435, and, Groups III-IV are all at least partially classified in class 424, subclass 184.1. Therefore, at the very least, the claims of Groups I-III should be rejoined, as should the claims of Groups III-IV, and ideally, the claims of Groups I-V should be searched and examined together as Group III serves as a linker group between Groups I and II and Groups IV and V, as evidenced by the classification assigned to each in the Office Action.

In summary, enforcing the present restriction requirement would result in inefficiencies and unnecessary expenditures by both the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, whereby a shortened patent term may result in any divisional applications filed). Restriction has not been shown to be proper, especially since it has been shown that the search and examination of each Group would be likely to be co-extensive and, in any event, would involve such interrelated art that the search and examination of the entire application can be made without undue burden on the Examiner. All of the preceding, therefore, mitigate against restriction.

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674544-2001**CONCLUSION**

In view of the amendments and remarks herein, reconsideration and withdrawal of the restriction requirement are requested. Early and favorable consideration of the application on the merits, and Allowance of the application are earnestly solicited.

Respectfully submitted,

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674544-2001**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

24. [Use of the] A method of preparing the pharmaceutical composition of claim 23,
wherein the pharmaceutical composition comprises a complex of claim 15 [in the preparation of
a medicament for use in immunising a patient against a disease or condition which is
characterised by the presence in the patient's body of cells displaying said recognition peptide
on the surface thereof; such as a tumour, or a malignant or auto-immune disease such as cancer
or leukaemia, an infectious disease such as a viral infection such as HIV infection, a bacterial or
microbial infection such as tuberculosis, or a parasitic infection such as malaria].

27. [Use of the] A method of preparing the pharmaceutical composition of claim 26,
wherein the pharmaceutical composition comprises a complex of claim 11 [in the preparation of
a medicament for the treatment of a tumour, or a malignant or auto-immune disease such as
cancer or leukaemia, or an infectious disease such as a viral infection such as HIV infection, or a
bacterial or microbial infection such as tuberculosis, or a parasitic infection such as malaria].